

Legislative Report Draft Outline



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CANNABIS SCIENCE TASK FORCE RECOMMENDATIONS

Cannabis Laboratory Quality Standards and
Proficiency Testing

Executive Summary

- Recommendations overview

Introduction

Background

- 2019 - House Bill 2052
- 2020 First report; recommendations to strengthen testing protocols for pesticides and creation of the ICT

Cannabis Science Task Force

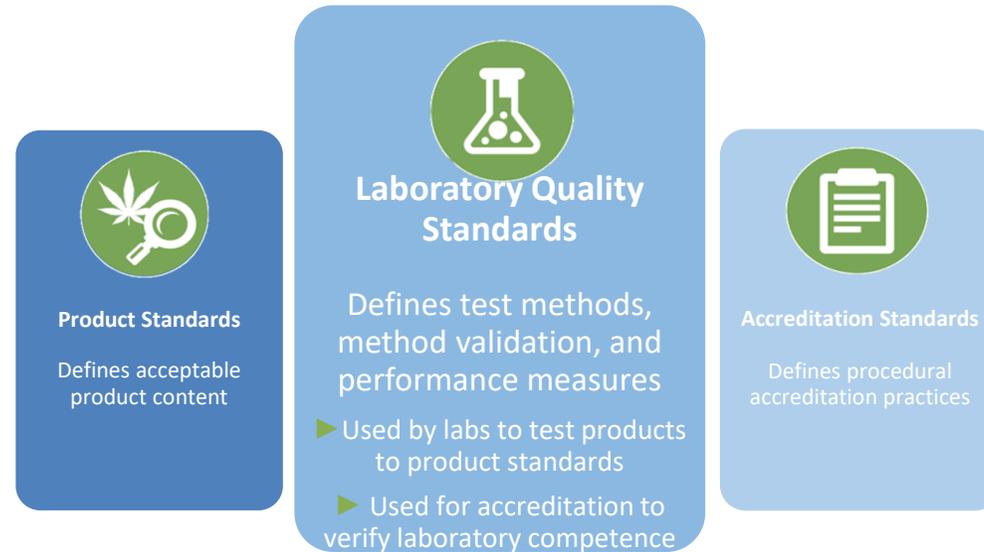
- Roles, structure, deliverables, timeline

Work Continuation

- Continued workgroups and focus areas
- Delivery of memo

Workgroup/Focus Area	Term	Status	Location of Final Recommendations
ANALYTICAL (PESTICIDES)	August 2019 – February 2020	Completed	Report #1
PROFICIENCY TESTING	August 2019 – March 2020	Completed	Report #2
HEAVY METALS	June 2020 – February 2021	Completed	Report #2
POTENCY	June 2020 – June 2021	Completed	Report #2
RESIDUAL SOLVENTS	March 2021 – June 2021	Completed	Report #2
MICROBIOLOGICAL	April 2021 – 2022	Continuing	Report #2; memo to WSLCB/ICT
MYCOTOXINS ^A	June 2021 – 2022	Continuing	Memo to WSLCB/ICT
MOISTURE CONTENT AND WATER ACTIVITY ^B	June 2021 – 2022	Continuing	Memo to WSLCB/ICT

Laboratory Quality Standards support Product Standards and Accreditation Standards



Defining Standardized Methods and Performance-Based Methods

- Descriptions of each premise

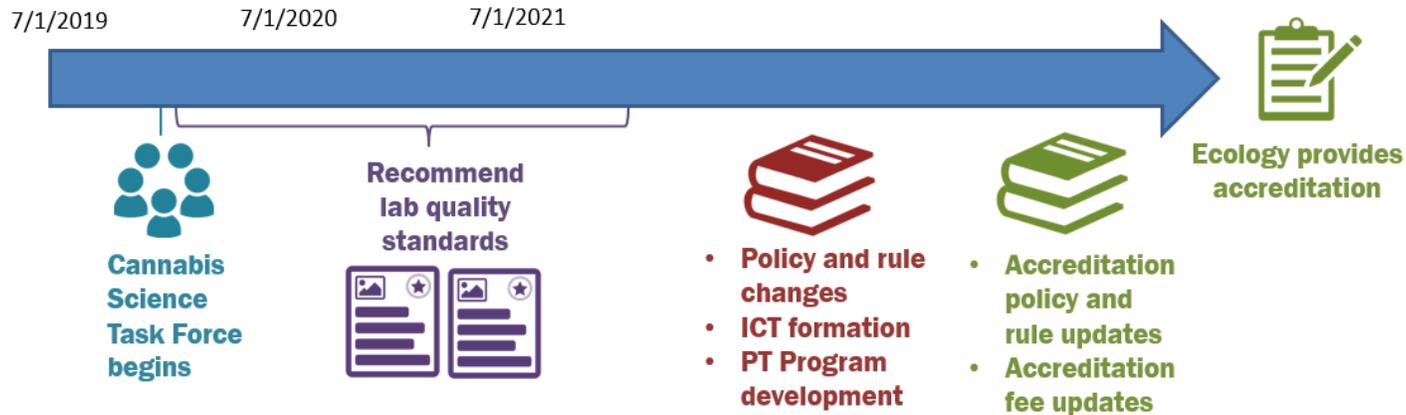
Importance of In-Matrix Proficiency Testing

- Integral role in regulatory testing; tool for accreditation
- What it means to be “in-matrix”
- How in-matrix PTs work

Barriers to Cannabis (In-Matrix) Proficiency Testing

- Federal and state barriers

Coordinated Actions and Accreditation Transfer



Interagency Cooperative Team

Genesis of the Interagency Cooperative Team

- As identified in first report
- Critical roles and responsibilities for pesticides

Additional ICT Roles and Responsibilities

- Roles to fill overarching gaps and challenges

Initial Integration of Laboratory Quality Standards Scientific support to put Laboratory Quality Standards into practice

On-going Method Maintenance

- As identified in method recommendation motions

Potency

- Method modification pathway development

Heavy Metals and Residual Solvents

- EPA method updates and expectations

Microbiology, Mycotoxins, Moisture, Water Activity and Foreign Matter

- Identifying need for finalizing remaining fields – research methods (if not completed), author guidance

Advancing the Science

- Anticipating technology development
- New cannabis products
- Outlined Pathway

Cannabis Proficiency Testing Program Facilitation

- Filling the in-matrix PT gap
- Removing barriers
- Action items

ICT Formation Framework

- Identifying progress completed and anticipated ahead



Laboratory Quality Standard Recommendations

- RCW 43.21A.735 mandated items
- Method, validation and performance measures, sampling and homogenization, PT, necessary regulatory updates

Potency Recommendations

Potency Recommendations

The Task Force recommendations for potency are as follows:

1. Appropriate approved testing methods: New York State (NYS) Department of Health (DOH) Medical Marijuana (MML)-301, revision 6 - Medical Marijuana Sample Preparation Protocols for Potency Analysis and NYS DOH MML-301, revision 6 - measurement of Phytocannabinoids in Medical Marijuana using HPLC-PDA (Appendix XX-xx).
 - a. When newer revisions of the approved test methods are published by the NYS DOH, the ICT shall review the newest version(s) prior to implementation. Document control and ultimate revision decisions shall be under the ICT authority. When new versions are authorized the laboratories would be required to update their methodology accordingly.
2. Method validation protocols: Method validation protocols are as established within each approved method.
 - a. A future validation pathway for laboratory-initiated modifications to increase method scope, beginning with minor matrices/products not included in the NYS DOH MML methods, shall be further developed by the ICT. The ICT pathway development shall incorporate the key attributes (Appendix XX-xx), and further develop the process using outlined process guidelines (Appendix XX-xx). Guidelines include method validation and review using steps necessitate the use of U.S. Food and Drug Administration document "Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products", Level 4 (Appendix XX) and AOAC Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis (Appendix xx).
3. Method performance criteria: Performance criteria are as established within in each approved method. The following additional performance measures and adaptations shall supersede, or be used in conjunction with the minimum method requirements, as appropriate.
 - a. The Task Force Potency Adaptations to the NYS DOH MML – 301 Revision 6 and NYSDOH MML – 300 Revision 6 methods shall be implemented to facilitate appropriate use of NYS methods (Appendix xx).
 - b. Potency determinations shall be performed on samples "as is" or as received by the lab.

Heavy Metals Recommendations

Residual Solvent Recommendations

Microbiological Recommendations

Proficiency Testing Recommendations

- Addressing comprehensive programmatic approach
- Covers critical matrices and identified matrix categories
- Recommendations to remove barriers for in-matrix PTs to be used in Washington

Reoccurring Challenges and Topics of Concern

Sampling Cannabis and Cannabis Products

Cannabis Reference and Blank Materials

Conclusion

Definitions

References

Appendices

Motions

Recommended Methods

Task Force Members

Cannabis Matrix Proficiency Testing Trial

- Proof-of-concept trial scoped by workgroup



Timeline and Next Steps

Task Force Report Timeline

